JUN 9 - 2005

510(K) SUMMARY

a. Company Name, Address:
TOGO MEDIKIT CO., LTD.
17148-6 Oaza-Hichiya Aza-
Kamekawa, Hyuga-shi,
Miyazaki-Ken, Japan 883-0062

b. Contact:
Kozo Nagayama, Director, Product Quality Center

c. Date Prepared:
August 2, 2004

d. Name of Device
Trade Name: SUPERCATH Z3V
Common Name: Intravascular catheter
Classification Name: Catheter, Intravascular (short-term)

e. Predicate Devices:
This device is substantially equivalent to "PROTECTIV PLUS Safety IV Catheter" (K030571) and Togo Medikit's Supercath IV (K864038) and Supercath AV (K854773).

f. Description of the Device:
The SUPERCATH Z3V intravascular catheter is intended to access vein or artery and to administer fluids. The SUPERCATH Z3V is designed for short-term use (less than 30 days), is intended to minimize inadvertent needlesticks or is intended to reduce accidental needlesticks.
The catheter hub has a built-in hemostatic valve, which assists compression hemostasis when the introducer needle is withdrawn following blood vessel puncture. The introducer needle is retracted into the telescope casing to prevent needle stick injury.

g. Statement of Substantial Equivalence:
The SUPERCATH Z3V is substantially equivalent to the PROTECTIV PLUS Safety IV Catheter (K030571) and Togo Medikit's Supercath IV (K864038) and Supercath AV (K854773. See Comparison Table 1.

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Table 1

Factor	Supercath Z3V	PROTECTIV
Same Intended Use	Yes	Yes
Polyurethane Catheter	Yes	Yes
Radiopaque Catheter	Yes	Yes
Flashback Visualization	Yes	Yes
Needle stick Injury Prevention Feature	Yes	Yes
Hemostatic Valve	Yes	No
EtO Sterilized	Yes	Yes
Single Sterile Wrapped	Yes	Yes
Multiple gauge Sizes and Needle Lengths	Yes	Yes

h. Conclusion

The SUPERCATH Z3V has the same intended use and similar technological characteristics as the PROTECTIV PLUS Safety IV Catheter (K030571) and similar component materials of prior Supercath models cleared by FDA. Thus, The SUPERCATH Z3V is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 - 2005

Mr. Kozo Nagayama
Director, Regulatory Affairs and Quality Assurance
Togo Medikit Company Limited
17148 Oaza-Hichiya Aza
Kamekawa
Miyazaki-Ken
Hyuga-Shi, 883-0062
JAPAN

Re: K050114
Trade/Device Name: Supercath Z3V
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 16, 2005
Received: May 17, 2005

Dear Mr. Nagayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

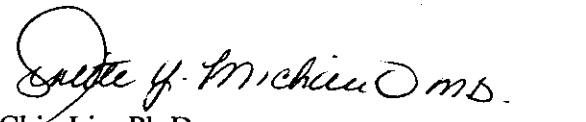
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) NUMBER (If known): K050114

Device Name: **Supercath Z3V**

Indications for Use:
The SUPERCATH Z3V intravascular catheter is intended to access vein or artery and to administer fluids. The SUPERCATH Z3V is designed for short-term use (less than 30 days), is intended to minimize inadvertent needlesticks or is intended to reduce accidental needlesticks.

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(Please do not write below this line – Continue on other page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050114